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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/827,190

04/19/2004

Gary J. Calton

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10/24/2008

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EXAMINER

MAEWALL, SNIGDHA

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

10/24/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/827,190	Applicant(s) CALTON ET AL.	
	Examiner Snigdha Maewall	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 8-20, 24-37 and 39-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8-20, 24-37 and 39-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

1. Receipt of Applicants remarks, arguments and RCE filed on 08/04/08 is acknowledged.

Rejections not repeated in this office action have been withdrawn.

Claims **1-3, 8-20, 24-37 and 39-54** are under prosecution.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-3, 8-20, 24-37 and 39-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lowry et al. (U.S. PGPUB 20010007878 A1) in view of Ukai *et al.*, (JP 411228450A).

Lowry et. al. teach a nutritional product in a composition comprising L-arginine for a person having renal failure. L-arginine is found to be an essential amino acid in patients with renal failure because of the role it plays in the synthesis of endothelium- derived relaxing factor (summary of invention). The composition

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can be cow-milk based, soy-based, or based on other proteins or nutrients.

Lowry et. al further suggest that the composition may also be administered via the normal oral route, and since the latter is preferred, the product's good taste is an important factor. Lowry et. al discloses that the nutritional product has moderate to high protein content and high calcium to phosphorus ratio. The composition contains vitamins, minerals and citric acid that is known in the art as flavoring agent and also water (paragraph 10, 14 and 16). The composition also typically contains emulsifiers and /or stabilizers such as carrageenan. (paragraph 25). Lowry et al. mention that L-arginine is well known for it's unpleasant taste and has detrimental effect of bitter elemental arginine on the taste of any formulation.

Although Lowry et. al. disclose adding one or more carboxylic acids to provide good taste to the product however, it does not teach utilizing carrageenan as a taste masking agent.

Ukai *et al.* disclose a composition in which the unpleasant taste of a medicine is masked by the addition of an anionic polymer. Ukai *et al.* further disclose that the unpleasant taste such as a bitter or irritating taste, can be found among orally administered medicines, such as antibiotics, antidementials, antiallergenics and more. Ukai *et al.* further teach that the anionic polymer which masks the unpleasant taste of the medicine is preferably a polysaccharide, such as carrageenan, chondroitin sulfate, or dextran sulfate.

Ukai *et al.* does not specifically disclose which form of carrageenan is to be employed. However, it is the position of the examiner that this is a limitation which would be routinely determined by one of ordinary skill in the art through minimal experimentation, as being suitable, absent the presentation of some unusual and/ or unexpected results based on the particular carrageenan employed. The results must be those that accrue from the specific limitations.

Furthermore, although the abstract of Ukai *et al.* does not disclose all of the specific types of formulations disclosed by applicant, they do disclose an oral composition. It is the position of the examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to use this taste masking composition in any type of formulation which required taste masking. The expected results would be the same, regardless of the specific type of formulation.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the taste masking composition taught by Ukai *et al.* for the masking of the bitter taste characteristically caused by L- amino acids. Ukai *et al.* teach a successful formulation, employed to mask the taste of active agents which cause a poor taste. It is unreasonable for Ukai *et al.* to list each and every active agent which may have a unsatisfactory taste. Furthermore, Lowry *et al.* teach that amino acids are well known in the art to have a characteristic bitter taste. One of ordinary skill in the art would certainly be motivated to use a composition known for success in masking poor taste of actives with an active known to have a poor taste. This would be clearly obvious to one skilled in the art. The expected result would be an amino acid

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formulation without a bitter taste. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

4. Claims 1-3, 8-20, 24-37 and 39-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ukai *et al.*, (JP 411228450A) in view of Acosta *et al.* (US Patent 5,550,146).

Ukai *et al.* disclose a composition in which the unpleasant taste of a medicine is masked by the addition of an anionic polymer. Ukai *et al.* further disclose that the unpleasant taste such as a bitter or irritating taste, can be found among orally administered medicines, such as antibiotics, antidementials, antiallergenics and more. Ukai *et al.* further teach that the anionic polymer which masks the unpleasant taste of the medicine is preferably a polysaccharide, such as carrageenan, chondroitin sulfate, or dextran sulfate.

Ukai *et al.* does not specifically disclose which form of carrageenan is to be employed. However, it is the position of the examiner that this is a limitation which would be routinely determined by one of ordinary skill in the art through minimal experimentation, as being suitable, absent the presentation of some unusual and/ or unexpected results based on the particular carrageenan employed. The results must be those that accrue from the specific limitations.

Furthermore, although the abstract of Ukai *et al.* does not disclose all of the specific types of formulations disclosed by applicant, they do disclose an oral

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composition. It is the position of the examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to use this taste masking composition in any type of formulation which required taste masking. The expected results would be the same, regardless of the specific type of formulation.

Additionally, Ukai *et al.* do not teach that the active which causes a poor taste in the formulation is an amino acid.

Acosta *et al.* is relied upon for the teaching in column 5, lines 35-36. It states that L-amino acid mixtures have a characteristic bitter taste. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the taste masking composition taught by Ukai *et al.* for the masking of the bitter taste characteristically caused by L- amino acids. Ukai *et al.* teach a successful formulation, employed to mask the taste of active agents which cause a poor taste. It is unreasonable for Ukai *et al.* to list each and every active agent which may have a unsatisfactory taste. Furthermore, Acosta *et al.* teach that amino acids are well known in the art to have a characteristic bitter taste. One of ordinary skill in the art would certainly be motivated to use a composition known for success in masking poor taste of actives with an active known to have a poor taste. This would be clearly obvious to one skilled in the art. The expected result would be an amino acid formulation without a bitter taste. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

5. Applicant's arguments with respect to claims 1-3, 8-20, 24-37 and 39-54 have been considered but are moot in view of the new ground(s) of rejection.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached from 8:30 Am to 5:00 PM on Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached on (571)-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Snigdha Maewall/

Examiner, Art Unit 1612

/Gollamudi S Kishore, Ph.D./

Primary Examiner, Art Unit 1612